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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/010,244	12/06/2001	Robert Sixto JR.	SYN-064 A	5798
24131	7590	11/01/2004	EXAMINER	
LERNER AND GREENBERG, PA			PANTUCK, BRADFORD C	
P O BOX 2480			ART UNIT	PAPER NUMBER
HOLLYWOOD, FL 33022-2480			3731	

DATE MAILED: 11/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/010,244	SIXTO ET AL.
	Examiner	Art Unit
	Bradford C Pantuck	3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 20 September 2004.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-12 and 26-33 is/are pending in the application.
  - 4a) Of the above claim(s) 13-25 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-12 and 26-33 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____.
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1, 2, 5, 6, 9-11, 27, and 29-33 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,037,021 to Mills et al. Regarding Claims 1, 2, 5, and 6, Mills' method includes grasping the region of tissue from an interior surface of the stomach, and configuring the region of tissue to create at least one fold of tissue. As described in Column 6, lines 14-41, the clip (209) inserted by Mills' clip applier (200) manipulates the tissue (216) into a fold and holds the invaginated section after being inserted. The clip is locked in place [Column 6, lines 31-33] and will not let the stomach resume its pre-folded condition, because of the way that the staple *pierces* and encompasses the fold of tissue [see Figures 5a-5c].

The clip has two arms and a bridge coupling the two arms, as shown in Attachment #2. The clip (209) slides over the body tissue (216) when the body tissue is sucked into the chamber (and into the clip), as shown in Figure 5a, and described in Column 6, lines 20-22. As the tissue is sucked into the clip, it will *contact* Arm A [as shown in Fig. 5a], and presumably the clip and the tissue will *slide relative to each other*. As shown in Figure 5C, body tissue is located between the two arms. The clip applies a compressive force to the body tissue [Column 6, lines 30-34]. The clip

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applier bends both of the arms, and one of them is bent through the whole thickness of the *both portions of tissue* [see progression from Figure 5a to 5c]. In Column 6, lines 22-28, Mills says that the remaining sections of the clip [i.e. Arm A and the bridge] are *deformed* (synonym for *bent*) during the application of the clip to the body tissue. Figure 5c shows Arm B being bent through the thickness of the body tissue. Thus both arms are bent during the application of the clip.

Mills discloses that his invention is intended to be used for “the attachment of materials or objects” to the *interior of the stomach* [Column 1, lines 44-45, 47-49].

2. Regarding Claim 9, Mills discloses compressing and clamping first and second portions of tissue (216) into contact with each other [see Fig. 5a] prior to sliding the clip and tissue sliding relative to each other. In Column 6, lines 9-10 Mills explains that prior to use the cavity is preloaded with the clip. Using logic, before the tissue can fit through the opening in the clipping device’s cavity (202) it must already be in a folded condition.
3. Regarding Claims 10, 11, and 30, the sliding and the bending are accomplished by using a single instrument. Column 6, lines 33-37 explain that the clip applier may contain a single clip or multiple clips. Further, only one [single] machine is used to carry out this process.
4. Regarding Claim 27, Mills discloses bending the piercing portion (in yellow – see Attachment #2) at acute angle  $\Phi$  relative to the *longitudinal axis of the tissue from which the fold was made*. A portion of the piercing portion is also bent at an acute angle  $\Theta$  relative to the *longitudinal axis of the fold* (Attachment #2).

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5. Regarding Claim 29, the clip applies *some force* to the fold, in the configuration shown in Fig. 5a, previous to being bent and pierced through the tissue. For example the clip will apply at least the force of its weight (mass x gravity) on the fold. Said clip does not exert a *compressive force* on the fold before:

“subsequently bending the piercing portion of at least one of the two arms through the first portion of the fold and at least partially through the second portion of the fold.”

6. Regarding Claims 31 and 32, Mills discloses clip (209) being advanced over a “double layer of tissue” [Column 6, line 22] having two portions: with reference to Figure 5a, it is evident that the fold of tissue has a first “layer” (portion) on the right and a second “layer” (portion) on the left. The folded tissue defines a longitudinal direction, which is the same direction as the midline of the fold (up/down in Fig. 5a). The piercing portions of the clip are initially oriented (Fig. 5a shows the initial configuration) along (synonyms: next to, adjacent to, by) the midline of the fold.

7. Regarding Claim 33, Mills clip is advanced over two thicknesses of body tissue: the fold consists of two portions of tissue as is evident from Fig. 5a. Each portion of tissue has a thickness. The clip has been advanced over the body tissue in Fig. 5a, and the piercing portion (bottom arm) is shown being bent at elbow adjacent to member (205) in Fig. 5b. The piercing portion is further bent by the anvil in Fig. 5c.

8. Claims 1, 3, 4, 12, 26, and 33 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by U.S. Patent No. 5,582,611 to Tsuruta et al. Regarding Claim 1, 3, 4, 26, and 33, the clip (22) has two arms and a bridge coupling the arms, as shown in

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Figure 61. The arms are the parallel parts and the bridge is the perpendicular portion connecting the arms [see Figures 42 and 43]. Body tissue is located between the two arms, such that the clip applies force to the body tissue. *Each arm is bent through the entire thickness of the body tissue, such that the tips of the two arms contact each other* [see progression from Figure 42B to Figure 42C].

9. Regarding Claim 12, the clip connects two separate pieces of tissue. "Tissue a" is connected to "tissue b." There is a gap between the two tissues, therefore they are considered to be separate, i.e. disunited or withdrawn from each other [Fig. 42A; Column 18, lines 5-10].

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,037,021 to Mills et al. in view of U.S. Patent No. 5,571,116 to Bolanos et al.

10. Regarding Claim 7, Mills discloses manipulating the region of tissue to create at least two adjacent folds of tissue [Column 6, lines 30-38]. Assumedly, one embodiment of Mills' device contains at least two staples so that they can be applied to folds of tissue close to the location of the first clip.

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11. Regarding Claim 8, Mills discloses grabbing the interior of the stomach with a grasping instrument and pulling on the interior of the stomach to cause invagination of the interior of the stomach. Using suction, the tissue is *pulled* into the cavity (202) in the clip applier [Column 6, lines 7-9; Fig. 5a]. During the clipping process, the interior of the stomach is held in the cavity of the grasping instrument *both by the vacuum and by the incidental contact between the tissue and the grasping instrument.* Further, Mills discloses holding the tissue mechanically [grabbing it], with piston 205 [see Fig. 1b].

With regards to Claims 7 and 8, Mills does not disclose that his procedure is done specifically in the part of the stomach called the *fundus*. However, Bolanos teaches that one would bend clips having two arms and a bridge completely through a fold of the fundus in the stomach *in order to help alleviate gastroesophageal reflux disease.* Mills teaches that in order to treat this disease effectively, one ought to attach the patient's lower esophagus to the patient's fundus [Column 2, lines 55-62]. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to perform the surgery disclosed by Mills to attach the lower esophagus to the fundus in order to alleviate gastroesophageal reflux disease in a patient, as taught by Bolanos.

***Allowable Subject Matter***

12. Claim 28 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Response to Arguments***

13. Applicant's arguments filed August 19, 2004 have been fully considered but they are not persuasive. Examiner disagrees with Applicant's contention that Mills "does not disclose a clip with two piercing portions" (Remarks/Arguments, p. 15 first full paragraph). Mills calls member (209) "a staple" [Column 6, lines 14-15]. As with any staple, Mills' staple has two arms with a *tip* at the end of each [Column 6, line 26]. Admittedly, only one of the tips is *shown* piercing tissue, but *both tips are capable of piercing tissue*. Staples are generally made of metal, which is stronger than tissue. Additionally, Mills describes both arms of the staple, and does not note any difference between them. The drawings [Figures 5a-5c] show the two arms of the staple being *identical*. The reader can consequently infer that both arms are essentially the same, having the same properties, materials, and capabilities. *Each arm has a sharp tip*. Therefore, if the first arm of the staple is capable of piercing tissue [see Fig. 5c], then the *second arm is capable of piercing tissue*.

Applicant even notes that Mills stapler is "very similar to a staple from, for example, a SWINGLINE desk stapler" (Remarks/Arguments, p. 17 last paragraph). Such a stapler certainly has two ends *capable of piercing tissue*.

14. Regarding Applicant's arguments in the last paragraph of page 17 and the first paragraph of page 18 (Remarks/Arguments), Examiner maintains his position. Applicant argues in those paragraphs that Mills' piercing portion is only bent after being driven through the tissue fold. For example in Figure 5c, the arm of the staple has been obviously bent by the anvil. However, the language Applicant uses in claim

31 to describe this aspect of the invention is “subsequently *bending* the piercing portion of at least one of the two arms *through* the first portion of the fold” (claim 1 is similar). Examiner contends that Mills’ staple piercing portion is *bent through the tissue* in that the piercing portion is bent *relative to the rest of the staple* while being driven through the tissue [compare the angle of the piercing portion relative to the rest of the staple in Fig. 5a to the angle in Fig. 5c]. Examiner suggest that Applicant use more precise language if Applicant means to claim that the piercing portion *itself* is bent.

Further, Examiner contends that the elbow adjacent to member (205) of Mills’ clip can be considered to be a *part of the piercing portion*. Applicant does not define where the portion starts and ends, and the term “portion” is quite broad. Perhaps Applicant could describe the piercing portion more fully, putting parameters on where it stops and starts.

15. Regarding the Tsuruta reference, Applicant argues that the clip is not advanced over body tissue (Remarks/Arguments, p. 20 last paragraph, p. 21 first para.). Examiner disagrees. Comparing Figure 42A and Figure 42C, it is evident that the clip has been *advanced* from a position far away from the tissue to a position in which it has pierced into and through the tissue. Regarding being “over” tissue, it is perfectly clear that the clip is *over the tissue*: that is the clip is located *on top of* or *above* the tissue while it is being advanced. Thus, the clip is advanced over tissue. In another sense the clip is advanced over/through tissue, while the arms of the clip are being driven through the tissue.

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16. Further regarding Tsuruta, Applicant argues that the clip is not advanced completely through the tissue (Remarks/Arguments, p. 19 last paragraph). Examiner disagrees. Figure 42C shows one clip arm having pierced completely through tissue portion b, and one clip arm having pierced completely through tissue portion a. Each portion (a, b) is a separate piece of tissue.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradford C Pantuck whose telephone number is (571) 272-4701. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*BCP*

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October 28, 2004

*Julian W. Woo*  
JULIAN W. WOO  
PRIMARY EXAMINER